K103822

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1. 510(k) Summary

Sponsor:	Synthes USA Products, LLC 1230 Wilson Drive West Chester, PA 19380
Date Prepared	April 20, 2011
Company Contact	Jeffrey L. Dow, JD Director, Clinical & Regulatory Affairs Synthes Biomaterials 484 356 9720 dow.jeffrey@synthes.com
Device Name:	Synthes Hemostatic Bone Putty
Classification:	Unclassified
Product Code	MTJ
Predicate Devices:	Ceremed, Inc. Ostene CT Soluble Hemostasis Implant Material K082491
Device Description:	Synthes Hemostatic Bone Putty (HBP) stops bone bleeding by establishing a physical barrier along the edges of bones that have been damaged by trauma or cut during the surgical procedure. When applied as directed, HBP forms a mechanical barrier that occludes the vascular openings in the damaged bone. This barrier prevents further bleeding during the surgical procedure and dissolves postoperatively, permitting normal tissue healing and bone regeneration. HBP is a blend of synthetic water soluble polymers that form a ready-to-use hemostatic agent that is substantially eliminated from the defect site in less than 48 hours. The constituents of Synthes Hemostatic Bone Putty and Ostene, the predicate, are similar. Ostene is comprised of a proprietary mixture of water soluble alkylene oxide copolymers. HBP is also comprised of water soluble alkylene oxide polymers. The remainder of HBP is a polysaccharide, carboxymethylcellulose (CMC), to improve handling. Ostene does not contain CMC.

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Non-clinical tests used for substantial equivalence comparison	• Cytotoxicity Study Using the ISO Elution Method – 1X MEM Extract • Mouse Peripheral Blood Micronucleus Study • ISO Modified Intracutaneous Study, Solution with Measurement • Genotoxcity: Bacterial Reverse Mutation Assay • Genotoxicity: Mouse Lymphoma Assay • ISO Guinea Pig Maximization Sensitization Test-Solution • Systemic Toxicity Study • An In Situ Study to Determine the HBP Resorption Rate in a Rat Craniotomy Model • *In Vivo* Resorption Rate of a Hemostatic Bone Putty Subcutaneously Implanted in the Rabbit at 2, 4, 7, 14 Days. • *In Vivo* evaluation of Hemostatic Bone Putty in a sheep vertebral body defect at 7 days • Evaluation of Hemostatic Bone Putty in a Sheep Vertebral Body Defect • An *In Vivo* Study to Determine Hemostatic Bone Putty Effect on Bone Healing In A Rat Craniotomy Model at 3, 6, and 12 Weeks
Intended Use:	Synthes Hemostatic Bone Putty is indicated for use as a water-soluble implant material for use in the control of bleeding from bone surfaces.
Substantial Equivalence:	Documentation is provided that demonstrates that Synthes Hemostatic Putty is substantially equivalent[1] to other legally marketed devices.

[1] The term "substantial equivalence" as used in this 510(k) notification is limited to the definition of substantial equivalence found in the Federal Food, Drug and Cosmetic Act, as amended, 21 USC §301 *et seq.*, and as applied under 21 CFR Part 807, Subpart E, under which a device can be marketed without pre-market approval or reclassification. A determination of substantial equivalence under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to, or in support of substantial equivalence herein, shall be construed as an admission against interest under the U.S. patent laws or their application by the courts.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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Synthes USA Products, LLC
% Jeffrey L. Dow, JD
1230 Wilson Drive
West Chester, Pennsylvania 19380

Re: K103822
Trade/Device Name: Synthes Hemostatic Bone Putty
Regulatory Class: Unclassified
Product Code: MTJ
Dated: April 21, 2011
Received: April 22, 2011

Dear Dr. Dow:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SYNTHES®

1. Indications for Use

510(k) Number (if known): K103822

Indications:

Synthes Hemostatic Bone Putty is indicated for use as a water-soluble implant material and for use in the control of bleeding from bone surfaces.

Prescription Use ___X___ (Per 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use_____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krone

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K103822